



12 -1-05

IFAS

PATENT  
ATTORNEY DOCKET NO. 089/US/PCT2/US-A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**CERTIFICATE OF MAILING**

I hereby certify under 37 C.F.R. 1.10 that this correspondence is being deposited with the United States Postal Service as Express Mail Label No. EV635673715 with sufficient postage on the date indicated below and in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[ X ] If checked, two copies of this correspondence are enclosed.

Date of Deposit: Nov. 30, 2005

Dawn M. Janelle

Signature

Dawn M. Janelle

Printed name of person mailing correspondence

Applicant: DONG, et al.

Art Unit: 1654

Serial No.: 10/629,261

Examiner: LUKTON, David

Filed: July 28, 2003

Title: ANALOGUES OF GLP-1

**FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT AND**  
**AUTHORIZATION TO**  
**CHARGE DEPOSIT ACCOUNT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed please find a Fifth Supplemental Information Disclosure Statement submitted in United States Patent Application Serial No. 10/629,261.

In an Office Action dated November 15, 2005, Examiner Lukton indicated that reference AE (HU P9501508) listed in the Information Disclosure statement of July 28, 2003 was provided without translation. Applicants submit herewith a full translation of HU P9501508 as well as a copy in Hungarian (reference DB). The abstract was the sole item provided by the Hungarian Examiner. Applicants respectfully note, however, that in an Office Action dated June 8, 2004 Examiner Lukton cited the "English Abstract of Hungarian patent P9501508 (1997) in a Notice of References Cited issued U.S. Application Serial No. 09/857,636, from which the present application claims benefit under

35 U.S.C. § 120 (37 C.F.R. 1.98(d)) and was therefore presumably in possession of the translated abstract.

Also in the Office Action dated November 15, 2005, Examiner Lukton indicated that references AQ, AR, AS, AU, AV, AX, AY, AZ, AAA and ABB listed in the Information Disclosure statement of July 28, 2003 were not provided. Applicants respectfully submit that copies of references AQ, AR, AS, AU, AV, AX, AY, AZ, AAA and ABB listed in the Information Disclosure statement of July 28, 2003 were previously submitted to the Patent and Trademark Office in connection with U.S. Application Serial No. 09/857,636, from which the present application claims benefit under 35 U.S.C. § 120 (37 C.F.R. 1.98(d)). As is evidenced by the enclosed Information Disclosure Statements in which Examiner Lukton intialed various references, Examiner Lukton was in possession of all references except for Thorens et al., 1996.

Also in said Office Action dated November 15, 2005, Examiner Lukton indicated that reference BA listed in Applicants' Second Supplemental Information Disclosure statement of October 27, 2004 and reference BC listed in Applicants' Third Supplemental Information Disclosure statement of March 16, 2005 were not provided. Applicants submit herewith copies of said references on a Fifth Supplemental Information Disclosure Statement.

For the convenience of the Examiner, however, Applicants submit again all literature references alleged to be missing from Applicants' Information Disclosure statement of July 28, 2003, Second Supplemental Information Disclosure statement of October 27, 2004 and Third Supplemental Information Disclosure statement of March 16, 2005. The references are listed on the enclosed PTO/1449 form submitted in Applicants' Fifth Supplemental Information Disclosure Statement (references DC through and included reference DN) along with the translation of the abstract of Hungarian Patent P9501508 (reference DB) and new citation DA.

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or  
(Whichever occurs last of the following: within three months of filing national application; within three months of date of entry of the national stage in international application; before the mailing date of first office action on the merits; or before the mailing of a first Office action after the filing of a request for continued examination)

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

[ ] under 37 CFR 1.97(d) together with:

[ ] a Statement under 37 CFR 1.97(e), as checked below, and

[ ] a Petition under 37 CFR 1.97(d)(2), and

[ ] a \$130.00 petition fee set forth in 37 CFR 1.17(i).

(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

[ ] Applicant requests that the attached IDS and cited reference(s) [ ] be placed in the application filewrapper.

(Filed after payment of issue fee)

[ ] The listed reference was cited in a communication from a foreign patent office in a counterpart foreign application.

[ X ] Enclosed herewith is form PTO/1449 (2 pages; reproduced form), with a copy of all references noted thereon.

[ ] Enclosed herewith is form PTO/1449 (1 page; reproduced form), with a copy of selected references noted thereon. This application was filed after June 30, 2003 and as such, copies of any United States Patent or Patent Publications are not enclosed.

[ ] Copies of the reference(s) [[ ]] noted on the enclosed form PTO/1449 were previously cited by or submitted to the Patent and Trademark Office in connection with U.S. Application Serial No. [[ ]], from which the present application claims benefit under 35 U.S.C. § 120 (37 C.F.R. 1.98(d)). Applicants request that copies of art in U.S. Application Serial No. [[ ]] cited on the enclosed PTO/1449 form be transferred to the present U.S. Application Serial No. [[ ]].

Concise Explanation Requirement (non-English references):

[ X ] The "concise explanation" requirement for reference(s) DB under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ X ] the enclosed English language abstracts.

It is requested that the information disclosed herein be made of record in this application, and that the references listed on the enclosed form PTO/SB/08B appear under the "References Cited" heading of any Patent which issues from this application, (MPEP 1302.12).

Statement Under 37 CFR 1.97(e):

[ ] Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

[ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Method of payment:

A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply.

No fee is believed to be due for this submission. However Applicant(s) hereby authorize the Commissioner to charge any fees that may be deemed to be due or to credit any overpayment to Deposit Account No. 50-0590. Two copies of this Statement are enclosed.

The Commissioner is hereby authorized to charge any deficiency in fees and credit any overpayment to Deposit Account 50-0590. Two copies of this Statement are enclosed.

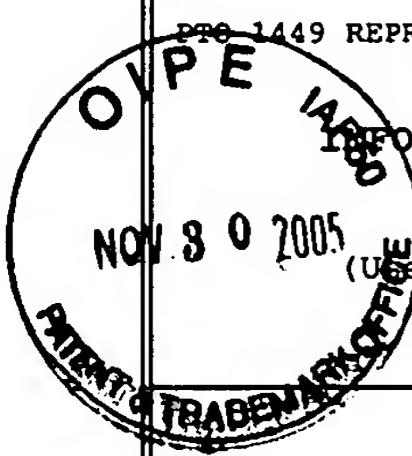
Respectfully submitted,

BIOMEASURE, INCORPORATED

Dated: Nov. 30 2005

By Pamela C Ball  
Pamela C. Ball, Agent for Applicant(s)  
Registration No.: 53,963

27 Maple Street  
Milford, Massachusetts 01757  
Phone: (508)478-0144  
Facsimile: (508) 473-3531



PTO 1449 REPRODUCED

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(use several sheets if necessary)

ATTORNEY DOCKET NO.  
089/US/PCT2/US-AAPPLICATION NO.  
10/629,261APPLICANT  
DONG, Zheng Xin.FILING DATE  
July 28, 2003GROUP/EXAMINER  
1654/Lukton, David

## U.S. PATENT DOCUMENTS

| EXAM-<br>INER<br>INI-<br>TIAL |  | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
|-------------------------------|--|-----------------|------|------|-------|---------------|----------------------------------|
|                               |  |                 |      |      |       |               |                                  |
|                               |  |                 |      |      |       |               |                                  |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE          | COUNTRY | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES NO |
|--|----|-----------------|---------------|---------|-------|---------------|-----------------------|
|  | DA | 00/34331        | Jun. 15, 2000 | PCT     |       |               |                       |
|  | DB | HU P9501508     | Feb. 28, 1997 | Hungary |       |               | X                     |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

|    |  |
|----|--|
| DC | ADELHORST, K. et al., "Structure-activity studies of glucagon-like peptide-1," 1994, J. Biological Chemistry, 269(9):6275-6278.  |
| DD | AHREN, Bo, et al.; "Effects of Glucagon-Like Peptide-1 on Islet Function and Insulin Sensitivity in Noninsulin-Dependent Diabetes Mellitus"; 1997; Journal of Clinical Endocrinology and Metabolism; Vol.82:2; Pages 473478                                  |
| DE | DEACON, C.F., et al.; "Dipeptidyl peptidase IV resistant analogues of glucagon-like peptide-1 which have extended metabolic stability and improved biological activity"; 1998; Diabetologia; Vol. 41; Pages 271-278  |
| DF | DEACON, C.F., et al.; "Dipeptidyl Peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon-Like Peptide 1 in the Anesthetized Pig"; 1998; Diabetes; Vol. 47; Pages 764-769  |
| DG | GUTNIAK, Mark, et al.; "Antidiabetogenic Effect of Glucagon-Like Peptide-1 (7-36) Amide in Normal Subjects and Patients with Diabetes Mellitus"; 1992; The New England Journal of Medicine; Vol. 326; Pages 1316-1322  |
| DH | MENTLEIN, R., et al; "Dipeptidyl-peptidase IV hydrolyses gastric inhibitory polypeptide, glucagon-like peptide-1 (7-36) amide, peptide histidine methionine and is responsible for their degradation in human serum"; 1993; Biochem; Vol. 214; Pages 829-835 |
| DI | NAUCK, M.A., et al.; "Effects of subcutaneous glucagon-like peptide 1 (GLP-1 [7-36 amide]) in patients with NIDDM"; 1996; Diabetologia; Vol. 39:2; Pages 1546-1553   |
| DJ | RACHMAN, J., et al.; "Near-normalisation of diurnal glucose concentrations by continuous administration of glucagon-like peptide-1 (GLP-1) in subjects with NIDDM"; 1997; Diabetologia; Vol. 40; Pages 205-211   |
| DK | RITZEL, U. et al., "A synthetic glucagon-like peptide-1 analog with improved plasma stability," 1998, J. Endocrinology, 159:93-102.  |
| DL | SUZUKI, S., et al.; "Comparison of the Effects of Various C-Terminal and N-Terminal Fragment Peptides of Glucagon-Like Peptide-1 on Insulin and Glucagon Release from the Isolated Perfused Rat Pancreas"; 1989; Endocrinology; Vol. 125:6; Pages 3109-3114  |

EXAMINER

DATE CONSIDERED

| PTO-1449 REPRODUCED   |    |  | ATTORNEY DOCKET NO.<br>089/US/PCT2/US-A | APPLICATION NO.<br>10/629,261        |       |               |                                  |
|---|----|--|---|--------------------------------------|-------|---------------|----------------------------------|
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>(Use several sheets if necessary) |    |  | APPLICANT<br>DONG, Zheng Xin.           |                                      |       |               |                                  |
|   |    |  | FILING DATE<br>July 28, 2003            | GROUP/EXAMINER<br>1654/Lukton, David |       |               |                                  |
| <b>U.S. PATENT DOCUMENTS</b>  |    |  |   |                                      |       |               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL   |    | DOCUMENT NUMBER  | DATE                                    | NAME                                 | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
| <b>FOREIGN PATENT DOCUMENTS</b>   |    |  |   |                                      |       |               |                                  |
|   |    | DOCUMENT NUMBER  | DATE                                    | COUNTRY                              | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES NO            |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
| <b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>                 |    |  |   |                                      |       |               |                                  |
|   | DM | THORENS, Bernard, et al.; "Structure and Function of the Glucagon-Like Peptide-1 Receptor"; 1996; Journal: Handbook of Experimental Pharmacology; Vol. 123; Pages 255-273                        |   |                                      |       |               |                                  |
|   | DN | TODD, J.F., et al.; "Glucagon-like peptide-1 (GLP-1): a trial of treatment in non-insulin-dependent diabetes mellitus"; 1997; European Journal of Clinical Investigation; Vol. 27; Pages 533-536 |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
|   |    |  |   |                                      |       |               |                                  |
| EXAMINER  |    |  |   | DATE CONSIDERED                      |       |               |                                  |